

REMARKS

Claims 1-15 are the pending claims in the present application. Applicants cancel, without prejudice, claims 7 and 11-13. Applicants add new claim 16. Support for the subject matter of this claim can be found throughout the specification. Explicit support for claim 16 can be found, for example, on page 9, lines 17-21. No new matter has been entered. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1. Applicants note that the previously filed amendments have been entered in full.
2. Claims 7 and 11-15 are objected to under 37 CFR 1.75 (c) for allegedly being in improper form. Applicants' cancellation of claims 7 and 11-13, and Applicants' amendment to claim 14 are believed to obviate the objection.
3. Claims 1-4, 7 and 8 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-19 of US Patent No. 6,207,718. Applicants will submit a terminal disclaimer, if necessary, upon indication of allowable subject matter.
4. Claims 1-4, 7 and 8 are rejected under 35 U.S.C. 103(a) as allegedly being obvious over Pepinsky et al. in view of Easton et al., and further in view of Usala et al. Applicants traverse this rejection, and furthermore Applicants contend that the rejection is moot in light of the amended claims.

Applicants maintain the arguments of record with respect to the combination of references which the Examiner alleges undermine the patentability of the claimed invention. Briefly, Applicants contend that the combination of references cited by the Examiner fail to disclose the particular combination of elements presently claimed. Nevertheless, to expedite prosecution of claims directed to commercially relevant embodiments of Applicants' invention, Applicants have amended the claims to more particularly point out an additional constituent of the claimed pharmaceutical compositions. Specifically, Applicants have amended the claims to more particularly point out that the pharmaceutical composition contains arginine or arginium ions within a particular concentration range. Support for this subject matter can be found on

page 6, lines 12-27. Applicants amendments are not in acquiescence to the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope.

Applicants' amendments to the claims are believed to render the rejection moot. Specifically, the cited references provide no guidance that would direct one of skill in the art to (a) select the particular buffer recited in the amended claims and (b) to formulate a composition containing the particular buffer within a particular concentration range. Applicants note that the concentration range recited in the amended claims does not merely blanket all physiologically relevant concentrations. In fact, not only does the application discuss broader possible concentration ranges, but the application also recites various distinct concentrations and concentration ranges depending on the particular buffer selected (see, for example, page 9, lines 12-21). Nothing in the cited references assists one of skill in the art in choosing from amongst these and other known buffers to select a particular buffer and concentration range, as required by the amended claims. Accordingly, the cited references fail to render the claimed invention obvious, and reconsideration and withdrawal of the rejection is respectfully requested.

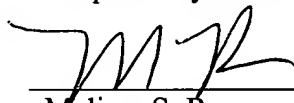
CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945, under Order No. CIBT-P01-097.**

Respectfully Submitted,

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